

COMMONWEALTH OF MASSACHUSETTS**DEPARTMENT OF PUBLIC HEALTH****Clinical Laboratory Program**

99 Chauncy Street, Boston, MA 02111

(617) 753-8060 (617) 753-8096 - Fax

Notification of Changes

Federal and State laboratory regulations require notification of changes be communicated according to the chart below. The appropriate mechanism for notification is to send written communication to the address noted above. Letter must be signed by the responsible party and must include an effective date.

CHANGE IN:	NOTIFICATION PERIOD		COMMENTS
	CMS	STATE	
OWNERSHIP	Within 30 days	15 days in advance	Include effective date
LOCATION	Within 30 days	15 days in advance	Include effective date
DIRECTOR	Within 30 days	Within 30 days	Include qualifications and effective date
NAME	Within 30 days	Within 30 days	Include effective date
TECHNICAL SUPERVISOR	Within 30 days	Within 30 days	Include qualifications and effective date
GENERAL SUPERVISOR	Not required	Within 30 days	Include qualifications and effective date
CHANGE IN SPECIALTY SUBSPECIALTY AREAS	Within 6 months	Prior to addition	State licensure approval is REQUIRED prior to the introduction of a new testing area Include: (1) PT enrollment information, (2) QC protocol, (3) check payable to COMMONWEALTH OF MASSACHUSETTS for \$300 per specialty added
SIGNIFICANT CHANGES TO THE PHYSICAL FACILITY	Not required	Within 30 days	After initiation of such changes
ADDITION OF A BLOOD COLLECTION STATION	Not required	Prior to opening	All Blood Collection stations must be APPROVED by the State before opening and MUST be associated with a LICENSED/APPROVED laboratory
ADDITION OF A SATELLITE / MULTISITE LABORATORY	Within 30 days	Prior to opening	All Satellite laboratories must be APPROVED by the State before opening and may only be associated with a PHYSICIAN OFFICE LABORATORY
CLOSURE OF LABORATORY	Effective date of closure	Effective date of closure	Include: (1) LOCATION where records will be stored, (2) PERSON responsible for the records and (3) Effective Date of closure

CMS regulations allow a new facility to operate as soon as the required fees have been received and processed (approximately 10 days after check has been mailed to the CMS lock-box).

STATE regulations require that a laboratory and/or all associated ancillary services [e.g. blood collection stations, satellites] be licensed **BEFORE** any testing is performed or services provided.